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| 10/571,600 | 07/05/2006 | Ahd Hamidi | 2001-1437 | 9771 |

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| EXAMINER | |
|---|---|
| ARCHIE, NINA | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/571,600 | HAMIDI ET AL. | |
| | Examiner | Art Unit | |
| | Nina A. Archie | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8,19 and 21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,19,27,29,31,35 and 36* is/are rejected.

7)☒ Claim(s) *21-26,28,30 and 32-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2008 has been entered.

### *Amendment Entry*

2. The amendment filed June 3, 2008 has been entered. Claims 8, 19, and 24-26, 32-34 have been amended. Claims 1-7, 9-18, and 20 have been cancelled.

### *Withdrawal of Rejection*

3. The rejection of claims 7-8, 19, 24-26, and 32-34 under 35 U.S.C. 112, first paragraph has been withdrawn in view of applicant's amendments and applicant's cancellation of claim (7).

4. The rejection of claims 7-8, 19, 23 and 31 under 35 U.S.C. 102 (b) as being anticipated by Ellwood et al US Patent 5,563,051 Date October 8, 1996 has been withdrawn in view of applicants amendments, arguments, and cancellation of claim (7).
.

5. The rejection of claims 7, 21-23, and 28 under 35 U.S.C. 103(a) as being as being unpatentable over Ellwood et al US Patent 5,563,051 Date October 8, 1996 in view of Hasler et al US Patent 6,891,037 (US Filing Date October 6, 1999), Lander et al

US Patent No. 6,410,025 Date June 25, 2002 has been withdrawn in view of applicants' amendments, and cancellation of claim (7).

***Response to Arguments***

6. Applicant's arguments with respect to 8, 19, 27, 29-31, and 35-36 have been considered but are moot in view of the rejections in the previous office action.

***Claim Rejections Maintained***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 8, 19, 27, 29-31, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellwood et al US Patent 5,563,051 Date October 8, 1996 in view of

Hasler et al US Patent 6,891,037 (US Filing Date October 6, 1999), Lander et al US Patent No. 6,410,025 Date June 25, 2002.

**Applicant arguments**:

-ELLWOOD et al. pertain to the production of hyaluronic acid by the fermentation of Streptococcus. ELLWOOD et al. fail to anticipate the present invention at least by the following aspects:

Anionic surfactant

- ELLWOOD et al. do not use alcohol in combination with the anionic surfactant, whereas the present invention does.
- ELLWOOD et al. use an anionic surfactant to lyse the cell and therefore extract the cell and therefore extract the polysaccharide from the biomass, whereas in the present invention, an anionic surfactant is used to precipitate impurities.

Cationic surfactant

- ELLWOOD et al. use a cationic detergent to get rid of nucleic acids by precipitating them, whereas the invention uses cationic detergent to precipitate the polysaccharide.

The claims of the present invention are therefore clearly not anticipated by ELLWOOD et al.

Regarding unpatentability, there are differences between claims of the present invention and ELLWOOD et al. in the way that the anionic and cationic surfactants are used in the purification process of the present invention.

HASLER et al. and LANDER et al. both pertain to a purification process with a single step, as summarized below. Both HASLER et al. (Example I) and LANDER et al. (Examples 1 and 2) start from a polysaccharide powder(s) or solution that have been (partially) purified using a classical purification process. They carry out one single purification step on the dissolved powder(s) or the solution, in a suitable aqueous solvent. Both documents do not teach or infer to modify the "classical purification process" that was first carried out. One of skill and creativity in the art would fail to combine ELLWOOD et al. with LANDER et al. for at least the following reasons.

LANDER et al. use as the sole purification step a precipitation of the polysaccharide using a cationic detergent. The precipitated polysaccharide is subsequently dried and dissolved into an organic solvent to be chemically derivatized and conjugated. ELLWOOD et al. use a cationic detergent in a multistep process and for a distinct goal different from that of LANDER et al. (see above, and in LANDER et al. Background of the Invention " accommodate the transition from an aqueous to an organic solvent. ."). There is no teaching or inference in ELLWOOD et al. to use a cationic detergent in another way, let alone to use a cationic detergent the way LANDER et al. did. Furthermore, there is no teaching or inference in LANDER et al. to modify its single step process into a multistep process. Therefore, one of ordinary skill and creativity would not combine ELLWOOD et al. and LANDER et al. Even if the skilled and creative person would hypothetically combine ELLWOOD et al. and LANDER et al., this person would still not arrive at the present invention, since none of these references disclose or infer the use of an anionic detergent in the presence of alcohol.

Furthermore, the skilled and creative person would never combine ELLWOOD et al. with HASLER et al. for at least the following reasons. HASLER et al. use as the sole purification step an anionic detergent in combination with alcohol to precipitate the endotoxins present in a polysaccharide fraction. ELLWOOD et al. use an anionic detergent in a multistep process and for a goal fundamentally different from that of HASLER et al. (see above). There is no teaching or inference in ELLWOOD et al. to use an anionic detergent in another way, let alone to use an anionic detergent the way HASLER et al. did. Furthermore, there is no teaching or inference in HASLER et al. to modify its single step process into a multistep process. Therefore, the skilled person would not combine ELLWOOD et al. with HASLER et al.

Also, even if one of skill and creativity in the art could combine ELLWOOD et al. with LANDER et al. and HASLER et al., there is no indication of what the resulting process would look like. A one-step process? A multistep process? To infer such a process would only be achievable by hindsight reconstruction.

In contrast, the present invention is a combination of steps combining several features. In contrast:

- ELLWOOD et al. pertain to a multistep purification process, where an anionic and a cationic detergent are used in a distinct way that is different from that of the present invention.

- HASLER et al. pertain to using anionic detergent in the presence of alcohol as a sole purification step.

- LANDER et al. pertain to the sole of a cationic detergent to precipitate the polysaccharide as a sole purification step.

However, the combination of steps in the claims of the present invention is neither disclosed nor inferred in the applied art references.

One of ordinary skill and creativity would thus fail to produce independent claims 8 and 19 of the present invention from a knowledge of ELLWOOD et al., HASLER et al. and LANDER et al. A prima facie case of unpatentability has thus not been made.

**Examiner's Response to Applicant's Arguments:**

Applicant's arguments have been fully considered but are not deemed to be persuasive. Examiner accepts amendments that have been made to claims. In response to applicant's arguments the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). This is why the references are combined under 35 U.S.C. § 103(a). Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Ellwood et al teach the following below.

-After the fermentation process (recovering a polysaccharide from a fermentation broth). The hyaluronic acid (HA)extracted with an aqueous medium containing an anionic surfactant such as sodium dodecyl sulphate. A surfactant may be added at a concentration of from 0.01 to 0.05% (w/v) and preferably at a concentration of 0.02% (w/v).

-The residual biomass is then separated from the aqueous solution by filtration. After the filtration, a solution of HA is obtained and this solution may be purified by diafiltration to remove low molecular weight impurities and it is necessary in this step to use an ultrafiltration membrane with an appropriate molecular weight cut off. The filtered solution containing the dissolved HA is diafiltered against purified water and the filtrate is continuously discarded after the diafiltration, the molarity and pH of the solution of HA adjusted.

-If a product of medical grade is required, the process may include an optional step of precipitating nucleic acids from the solution. This is achieved by the addition of a cationic surfactant such as cetyl pyridinium chloride. The cationic surfactant may be added as a dilute aqueous solution; for example a 1% (w/v) solution of cetyl pyridinum chloride may be added in a volume ratio of 1:60 to the solution. The precipitated nucleic acid may be removed by filtration. If this step is used, subsequent processing must be carried out.

-After this optional stage, or, if the optional stage is not used, after the adjustment of the molarity and pH of the solution, HA is precipitated by the addition of a non-solvent, such as isopropyl alcohol. The precipitated HA is filtered off and the filtrate discarded. Further purification of the HA product can be achieved by redissolving the HA and then reprecipitating by addition of a non-solvent as described above.

-Example 1 discloses fermentation medium is continuously withdrawn from the fermenter. Sodium dodecyl sulphate is continuously fed to achieve final concentrations of 0.025% (w/v) of sodium dodecyl sulphate and 1% (v/v). The solution is then processed by diafiltration against purified water to remove residual materials from the

culture medium, with sodium dodecyl sulphate. A 1% (w/v) solution of cetyl pyridinium chloride is then added in a ratio of about 1:60 by volume. The nucleic acids thus precipitated are removed by pumping the solution through depth filters. The filtered solution of hyaluronic acid thus obtained is then continuously mixed in with isopropyl alcohol. The precipitated hyaluronic acid is separated from the aqueous solution in a basket filter. The filtrate is discarded. The recovered hyaluronic acid is redissolved to give an HA concentration of 0.2% w/v). The hyaluronic acid is again precipitated from this solution by addition of isopropyl alcohol in the same way as previously. The precipitated hyaluronic acid is washed with isopropyl alcohol and the washings are discarded.

Ellwood teaches a fermentation process, then HA extracted with an aqueous medium containing an anionic surfactant such as sodium dodecyl sulphate. Ellwood et al also teaches, that if a product of medical grade is required, the process may include an optional step of precipitating nucleic acids from the solution achieved by adding a cationic surfactant. Ellwood et al teaches that after the optional stage, or, if the optional stage is not used, after the adjustment of the molarity and pH of the solution, HA is precipitated by the addition of a non-solvent, such as isopropyl alcohol. The precipitated HA is filtered off and the filtrate discarded. Further purification of the HA product can be achieved by redissolving the HA and then reprecipitating by addition of a non-solvent as described above. Furthermore, Example 1 teaches that after the addition of anionic surfactant and cationic surfactant to HA, HA is precipitated from the solution by addition of isopropyl alcohol.

Although Applicants states that Ellwood et al. use a cationic detergent to get rid of nucleic acids by precipitating them, whereas the invention uses cationic detergent to precipitate the polysaccharide. Examiner disagrees; the claim is drawn to employing a cationic detergent to precipitate the polysaccharide. Therefore the limitation has been met.

Although Applicants states Ellwood et al do not use alcohol in combination with the anionic surfactant, whereas the present invention does. Applicants also state that

Ellwood et al. use an anionic surfactant to lyse the cell and therefore extract the cell and therefore extract the polysaccharide from the biomass, whereas in the present invention, an anionic surfactant is used to precipitate impurities. Examiner disagrees, the claim is drawn to alcohol precipitation in the presence of anionic detergent. As discussed above, Ellwood et al teach HA is precipitated from the solution by addition of isopropyl alcohol after the addition of anionic surfactant. Therefore the limitation have been met.

Examiner disagrees with Applicant's assertion of one of skill in the art would not combine Ellwood et al with Lander et al and Hasler et al. Ellwood et al is discussed above and in the previous office action.

Hasler et al teach a method for the isolation of polysaccharides, in particular for the separation of endotoxins from capsule polysaccharides of gram-negative bacteria such as Haemophilus influenzae (type b) (see abstract, column 2 lines 17-20). Hasler et al teach a method for the isolation of polysaccharides, wherein the following steps are carried out: (a) mixing of a bacterial polysaccharide fraction with a anionic surfactant detergent solution; (b) addition of alcohol to a final concentration at which endotoxins are precipitated and which is below the concentration at which the polysaccharide precipitates; (c) mixing the solution; (d) filtering the solution by way of a deep bed filter, wherein the endotoxins are separated and remain in the filter; (e) separation of the polysaccharide from detergent and alcohol (claim 1).

Lander et al teach that bacterial polysaccharides are isolated then precipitated with a long chain detergent (see abstract). Lander et al teach that the cationic detergent is cetyltrimethylammonium bromide (CETAB) (hexadecyltrimethyl ammonium bromide) (see column 2). Lander et al teach that by-products, any unreacted derivatized polysaccharide and excess reagents are removed by diafiltration against volumes of deoxycholate (see column 4).

Therefore one would have been motivated It would have been prima facie obvious at the time the invention was made to use a method for recovering a HA as taught by Ellwood et al and to substitute HA for a polysaccharide obtained from a

fraction of Haemophilus influenza type b as taught by Hasler et al because Ellwood et al teach if a product of medical grade is required, the process may include an optional step of precipitating nucleic acids from the solution achieved by the addition of a cationic surfactant and Hasler et al et al teach that Haemophilus influenza type is used in a polysaccharide vaccine and also both teach isolation of polysaccharides to obtain a purified polysaccharide.

Also one would have been motivated at the time the invention was made to use in a method anionic surfactant such as sodium dodecyl sulphate and cationic surfactant such as cetyl pyridinium chloride as taught by Ellwood et al and to substitute an anionic detergent comprising sodium deoxycholate and a cationic surfactant comprising hexadecyltrimethyl ammonium bromide as taught by Lander et al because both Ellwood et al and Lander et al teach isolation of polysaccharides to obtain a purified polysaccharide.

Also one would have been motivated at the time the invention was made to employ surfactants to precipitate a polysaccharide to obtain polysaccharide fractions as taught by Ellwood et al further in view of Hasler et al because both teach isolating polysaccharide for purification purposes.

As outlined previously, the claims are drawn to a method for recovering a polysaccharide from a fermentation broth comprising: mixing a polysaccharide fraction with an anionic detergent; and adding alcohol until a concentration is below a concentration necessary for precipitating the polysaccharide; employ a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below the concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate; and subjecting

it to concentration and diafiltration (claim 8); a method for recovering a polysaccharide from a fermentation broth, comprising: employ a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below the concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate; and subjecting it to concentration and diafiltration (claim 19).

Ellwood et al is relied upon as set forth supra. However, Ellwood et al does not teach a method, wherein the anionic detergent comprises sodium deoxycholate, wherein the cationic surfactant comprises hexadecyltrimethyl ammonium bromide, wherein the polysaccharide is obtained from Haemophilus influenza type b.

Hasler et al teach a method for the isolation of polysaccharides, in particular for the separation of endotoxins from capsule polysaccharides of gram-negative bacteria such as Haemophilus influenzae (type b) (see abstract, column 2 lines 17-20). Hasler et al teach that the removal of endotoxins is a critical and decisive step during the purification of polysaccharides and the method for the separation of endotoxins from bacterial polysaccharides which is used most often according to the state of the art is based on the extraction with phenol, which, if necessary, has to be repeated several times until the endotoxin content is as required by health authorities (see column 1). Hasler et al teach a method for the Isolation of polysaccharides which is simple, economically useful and less injurious to health thus the invention relates to a method for the isolation of polysaccharides, wherein the following steps are carried out (a) mixing of a bacterial polysaccharide fraction with a detergent solution (anionic detergent); (b) addition of alcohol to a final concentration which is below the concentration at which the polysaccharide precipitates; (c) mixing the solution; (d)

filtering the solution; (e) separation of the polysaccharide from detergent and alcohol (see column 1).

Lander et al teach that bacterial polysaccharides are isolated then precipitated with a long chain detergent (see abstract). Lander et al teach that the cationic detergent is cetyltrimethylammonium bromide (CETAB) (hexadecyltrimethyl ammonium bromide) (see column 2). Lander et al teach that by-products, any unreacted derivatized polysaccharide and excess reagents are removed by diafiltration against volumes of deoxycholate (see column 4).

It would have been prima facie obvious at the time the invention was made to use a method as taught by Ellwood et al and to include, wherein the polysaccharide is obtained from Haemophilus influenza type b as taught by Hasler et al because both Ellwood et al and Hasler et al teach isolation of polysaccharides to obtain a purified polysaccharide. It would also have been prima facie obvious at the time the invention was made to use a method as taught by Ellwood et al and to include an anionic detergent comprising sodium deoxycholate and a cationic surfactant comprising hexadecyltrimethyl ammonium bromide as taught by Lander et al because both Ellwood et al and Lander et al teach isolation of polysaccharides to obtain a purified polysaccharide.

***Status of the Claims***

8. No claims are allowed.

Claims *8, 19, 27, 29, 31, 35 and 36* are rejected.

Claims 24-26, 30, and 32-34 are objected as being dependent from a rejected base claim.

Claims *21-23 and 28* are objected as being dependent on a cancelled claim.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisors, Shannon Foley can be reached on 571-272-0898 and Robert Mondesi at 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nina A Archie/
Examiner, Art Unit 1645/N. A. A./
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/Mark Navarro/

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